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NRT
NORDISK RØNTGEN TEKNI

K033486

510(K) Summary of Safety and Effectiveness

As required by section 807.92

Date Prepared: October 3, 2003

Applicant: NRT - Nordisk Roentgen Teknik A/S
Quality Assurance Specialist
Jan Malling

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Contact: Tel.no. +45 8628 3500
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Device name: GE Precision MPi

Common name: Universal tilt-C

Classification: Class II, sec.21CFR892.1650, Radiology, Image-intensified fluoroscopic x-ray system

Product code: JAA

Legally marketed device to which we claim equivalence:
Philips MultiDiagnost 4, 510(K) no. K961374.

Device Description:
The GE Precision MPi tilt-C consists of an X-ray Generator, Right or Left side suspended Angulations Table with X-ray Tube, Collimator and Image Intensifier, Operators console, and Digital Imaging/Archive system.

Intended Use:
The GE Precision MPi is an all-digital multipurpose tilt-C X-ray system, intended for a multitude of diagnostic procedures, including: R&F, radiology, fluoroscopy, interventional procedures, vascular and non-vascular procedures, and specialized applications including angiographic studies

Summary of technological differences
There are no technological differences between the GE Precision MPi and The MultiDiagnost 4. Many of the components used are currently available and have been chosen for the GE Precision MPi to ensure proven effectiveness and safety.

Conformance:
The GE Precision MPi will conform to the applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL60601-1, IEC60601-1 and applicable collateral and particular standards.

Conclusion:
We believe that the GE Precision MPi is substantially equivalent to the Philips MultiDiagnost 4. The GE Precision MPi and the Philips MultiDiagnost 4 is intended for the same type of clinical use and for the same group of users. The GE Precision MPi does not introduce any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NRT-Nordisk Roentgen Teknik A/S
% Mr. Heinz-Jörg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K033486
Trade/Device Name: GE Precision MPi
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 JAA
Dated: October 31, 2003
Received: November 4, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033486

Device Name: GE PRECISION MPi

Indications For Use:

The GE Precision MPi is a multi-purpose system that can perform general R&F, radiography, fluoroscopy, interventional and angiography procedures/applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033486